AUG 1 0 2000

p. 1 of 2

K000114

510(k) SUMMARY
RS-4M+
May 15, 2000

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR 807.87.

1. **Applicant, Official Correspondent and Owner of 510(k)**

RS Medical
14401 SE First St.
Vancouver, WA 98684

Attn: Mike McGraw, Vice President, Research and Development
Telephone: (360) 892-0339
Fax: (306) 896-2566

Submitter of 510(k) and Consultants
Joel S. Faden, Ph.D., Inc.
11605 Hitching Post Lane
Rockville, MD 20852
Telephone: (301) 881-9139

Fax: (301) 881-9249

2. **Name of Device**

Trade/Proprietary Name: RS-4M+ Muscle Stimulator

Common/Usual Name: Muscle and Interferential Current Stimulator

Classification Name: 21 CFR 890.5850 "Powered Muscle Stimulator", Class II.

3. **Legally Market Predicate Devices**

The RS-4M+ is substantially equivalent[1] to its legally marketed predecessor the RS-4V (K990697) muscle stimulator and Stellar HS-04 (K973223) muscle stimulator.

---

[1] Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to refer to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. (Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355))

4. **Indications for Use**

Muscle Stimulation, Interferential and Non-Interferential Currents

- Relax muscle spasms
- Prevent or retard disuse atrophy
- Maintain or increase range of motion
- Increase local blood circulation
- Re-educate muscle
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Pain Relief, Interferential Current

- Relieve acute pain
- Relieve and manage chronic pain

5. **Device Description and Substantial Equivalence**

The RS-4M+, like a number of legally marketed predicate devices, incorporates traditional muscle stimulation and interferential current stimulation modalities into one unit. Only one modality may be operated at a time. The RS-4M+ is housed in a plastic enclosure. The front of the enclosure houses a character LCD display. The accessories provided with the RS-4M+ include the output cables, the electrode pads, and the AC Charging Adapter.

The RS-4M+ muscle stimulation modality operates at a specified 57.5 volts peak (+/-10% into a 500 ohm load) and 115 mA peak (+/-10% into a 500 ohm load) with a pulse width of 415 μSec.(maximum +/-10%) and a cycle frequency of 71 Hz(+/-5%). The pulses are bi-phasic. The waveform includes an on/off ramp, which slowly increases the pulse width to the desired setting.

The RS-4M+ interferential modality operates at a specified 100 mA peak (+/-10% into a 500 ohm load). The carrier and interferential signals are sine wave symmetric, balanced outputs with zero net charge. The interferential modality can operate in a true interferential mode (4 pad mode) or the signals can be pre-mixed and only the pre-mixed signals sent to the patient (2 pad mode). The interference signal frequency can be fixed (Continuous) or varied based on three selections (Variable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Mike McGraw
Vice President, Research and Development
RS Medical Corporation
P.O. Box 4656
Vancouver, Washington 98662-0656

Re: K000114
Trade Name: "RS-4M Plus" Stimulator
Regulatory Class: II
Product Codes: 89 IPF and 84 LIH
Dated: May 16, 2000
Received: May 17, 2000

Dear Mr. McGraw:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at

(301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

K000114

Device Name: RS-4M+ Muscle Stimulator

Indications For Use:

Muscle Stimulation, Interferential and Non-Interferential Currents

- Relax muscle spasms
- Prevent or retard disuse atrophy
- Maintain or increase range of motion
- Increase local blood circulation
- Re-educate muscle
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Pain Relief, Interferential Current

- Relieve acute pain
- Relieve and manage chronic pain

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Donna R. Vochmer
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000114